

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD., Plaintiff,)	
)	
v.)	
)	C.A. No. 21-1015 (GBW)
SAREPTA THERAPEUTICS, INC.,)	
Defendant.)	
)	
)	
SAREPTA THERAPEUTICS, INC., and)	
THE UNIVERSITY OF WESTERN)	
AUSTRALIA, Defendant and Counter-)	<div style="background-color: black; width: 150px; height: 1.2em;"></div>
Plaintiffs)	
)	
v.)	
)	
NIPPON SHINYAKU CO., LTD. and)	
NS PHARMA, INC., Plaintiff and Counter-)	
Defendants.)	

**NIPPON SHINYAKU CO. LTD. AND NS PHARMA, INC.’S MOTION FOR THE
ISSUANCE OF A REQUEST FOR INTERNATIONAL JUDICIAL ASSISTANCE
AND INCORPORATED MEMORANDUM OF LAW IN SUPPORT**

Plaintiff/Counter-Defendant Nippon Shinyaku Co. Ltd. and Counter-Defendant NS Pharma, Inc. (collectively, “NS”) respectfully move, pursuant to Federal Rule of Civil Procedure 28 and Article 3 of the Hague Convention of 18 March 1970 on the Taking of Evidence Abroad in Civil or Commercial Matters, 28 U.S.C. § 1781 (the “Hague Convention”), the Court to issue the attached Letter of Request (**Exhibit A**) to the Competent Authority of Australia to compel the testimony of Abbie Adams and Penny Meloni, who, upon information and belief, are citizens of and reside in Australia.

I. BACKGROUND

This patent infringement action involves antisense oligonucleotides (“ASOs”) for the treatment of Duchenne’s muscular dystrophy (“DMD”). Nippon Shinyaku, Co., Ltd. (“Nippon Shinyaku”) and NS Pharma, Inc. (“NS Pharma,” collectively with Nippon Shinyaku “NS”) are direct competitors of Sarepta Therapeutics (“Sarepta”)—each provide ASO-based therapies for the treatment of DMD. Sarepta and NS are the only companies with FDA clearance to market ASO therapies that induce exon 53-skipping for the treatment of DMD for patients in need thereof. Sarepta’s product is marketed under the name VYONDYS 53, and NS’s product is marketed under the name VILTEPSO®.

Nippon Shinyaku initiated this action alleging that Sarepta’s manufacture, use, and sale of VYONDYS 53 infringed its U.S. Patent Nos. 9,708,361, 10,385,092, 10,407,461, 10,487,106, 10,647,741, 10,662,217, and 10,683,322 (collectively the “NS patents”) (Second Am. Compl. ¶¶ 3, 92-164, D.I. 86.) Nippon Shinyaku also sought a declaratory judgment of invalidity University of Western Australia’s (“UWA”) U.S. Patent Nos. 9,994,851, 10,227,590, and 10,266,827 (collectively the “UWA patents”), which are licensed to Sarepta. (*Id.* ¶¶ 2, 76-91.) Sarepta and UWA filed counterclaims seeking a declaratory judgment of invalidity the NS patents and alleging that NS’s manufacture, use, and sale of VILTEPSO® infringed the UWA patents. (Am. Answer to Second Am. Compl. ¶¶ 1-2, 36-81, D.I. 195). NS denies infringement and alleges that the UWA Patents are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 101 et seq. relating to requirements for patentability. (Answer to Countercl. ¶¶ 1-2, 36-81, D.I. 200.)

The UWA patents name Drs. Stephen Donald Wilton, Sue Fletcher, and Graham McClorey as inventors. (Second Am. Compl. ¶ 49.) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Ms. Adams and Ms. Meloni are also co-authors of several peer reviewed publications related to exon-skipping treatments for DMD and are each named as inventors on International Application No. PCT/AU2010/001520, which is not a priority application to any of the asserted UWA patents but discloses antisense oligonucleotides for exon skipping to treat DMD, including several sequences that fall within the claimed genus of the UWA patents.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

In preparing this request for international judicial assistance, NS requested Sarepta and UWA's confirmation that it would not oppose this Motion. This motion is opposed by Sarepta.¹

II. LEGAL STANDARD

Australia and the United States are both signatories to the Hague Convention, which "prescribes certain procedures by which a judicial authority in one contracting nation may request evidence located in another nation." *In re Automotive Refinishing Paint Antitrust Litig.*, 358 F.3d 288, 299 (3d Cir. 2004). Under Chapter 1, Article 1, these procedures provide that a domestic court

¹ NS met and conferred with UWA's counsel on June 2, 2023. UWA's counsel could not confirm whether UWA would oppose this motion or provide a date by which they could do so.

may issue a “letter of request” to a foreign court for execution. Federal courts are inherently vested with authority to issue letters of request. *See* 28 U.S.C. § 1781.

While issuance of a letter of request is within the Court’s discretion, the “burden is not great for a party seeking a letter of request” and are “routinely issue[d] . . . where the movant makes a reasonable showing that the evidence sought may be material or may lead to the discovery of material evidence.” *Compagnie des Grands Hotels d’Afrique S.A. v. Starman Hotel Holdings LLC*, C.A. No. 18-00654-RGA, 2019 WL 3391971, at *2 (D. Del. July 26, 2019) (internal quotation marks, citation omitted). Courts consider five factors in determining whether issuance of a letter of request give due respect to international comity:

(1) the importance of the documents or information requested to the litigation; (2) the degree of specificity of the requests; (3) whether the information originated in the United States; (4) the availability of alternative means of securing the information; and (5) the extent to which noncompliance with the requests would undermine important interests of the United States, or compliance of the requests would undermine important interests of the state where the information is located.

Liqwd, Inc v. L’Oreal USA, Inc., Civ. No. 17-14-JFP-SRF, 2018 WL 11189616, at*2 n.1 (D. Del Nov. 16, 2018). Letters of request should be issued unless the Court finds good cause to justify denial. *See Ethypharm S.A. France v. Abbot Lab’ys*, 748 F. Supp. 2d 354, 358 (D. Del. 2010)

III. ARGUMENT

NS seeks to take evidence from two individuals who designed and optimized the ASOs for exon 53-skipping and performed experiments leading to the subject matter of the UWA patents through issuance and execution of the attached letter of request. On information and belief, the individuals are Australian nationals who currently reside within Australia and are subject to the jurisdiction of the Australian courts.

NS is unable to obtain testimony from these individuals through available U.S. procedures (e.g., a subpoena pursuant to Fed. R. Civ. P. 45). These individuals are percipient fact witnesses who possess information related to [REDACTED]

[REDACTED]—issues directly relevant to the parties’ dispute and material to NS’s claims and defenses. The importance of Ms. Adams and Ms. Meloni to the alleged inventions of the UWA patents is supported and demonstrated by [REDACTED]

[REDACTED] Namely, [REDACTED]

[REDACTED]

[REDACTED] Moreover, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Accordingly, both the [REDACTED]

confirm that their knowledge and testimony will not be duplicative or cumulative of Dr. Wilton’s.²

Although Ms Adams and Ms. Meloni performed their work in Australia, it was used to obtain the United States patents that Sarepta and UWA have asserted in this action.

Ms. Adams and Ms. Meloni are “not parties to the lawsuit, have not voluntarily subjected themselves to discovery, are citizens of [Australia] and are not otherwise subject to the jurisdiction of the Court.” *Tulip Computers Int’l B.V. v. Dell Computer Corp.*, 254 F. Supp. 2d 469, (D. Del. 2003). Accordingly, these factors “weigh in favor of proceeding under the Hague Evidence Convention,” and indeed, “application of the Hague [Evidence] Convention, which encompasses

² Dr. Wilton is the only named inventor of the UWA patents that Sarepta and UWA have agreed to make available for deposition thus far.

principles of international comity, is virtually compulsory.” *Id.* (quoting *Orlich v. Helm Brothers, Inc.*, 160 A.D.2d 135, 143, 560 N.Y.S.2d 10 (N.Y.A.D. 1990)).

The letter of request does not place an undue burden on these two witnesses. The topics for examination are narrowly tailored to seek the witnesses’ personal knowledge concerning the [REDACTED] the aforementioned [REDACTED] issues and do not otherwise seek information on tangential matters to this case, or for the production of documents. The topics have been prepared to limit the testimony to evidence that may be adduced at trial, rather than constituting pre-trial discovery, in view of Australia’s declaration under Article 23 of the Hague Convention.

IV. CONCLUSION

As set forth above, the requested oral examinations are relevant to NS’s claims and defenses, and issuance of this letter of request serves the interests of justice. NS respectfully requests that its Motion be granted and that the Court sign and issue the letter of request attached as Exhibit A. Once the Court has done so, counsel for NS shall convey the signed letter to the Supreme Courts in Australia for execution.

Dated: June 5, 2023

Respectfully submitted,

MORGAN, LEWIS & BOCKIUS

Amanda S. Williamson (admitted <i>pro hac vice</i>)	<u>/s/ Amy M. Dudash</u>
Christopher J. Betti (admitted <i>pro hac vice</i>)	Amy M. Dudash (DE Bar No. 5741)
Krista V. Venegas (admitted <i>pro hac vice</i>)	1201 N. Market Street
Wan-Shon Lo (admitted <i>pro hac vice</i>)	Suite 2201
Maria E. Doukas (admitted <i>pro hac vice</i>)	Wilmington, Delaware 19801
Zachary Miller (admitted <i>pro hac vice</i>)	Telephone: 302.574.3000
Guylaine Haché (admitted <i>pro hac vice</i>)	Fax: 302.574.3001
Michael T. Sikora (admitted <i>pro hac vice</i>)	amy.dudash@morganlewis.com
110 N. Wacker Drive, Ste 2800	
Chicago, IL 60601	
Telephone: 312.324.1000	
Fax: 312.324.1001	

*Attorneys for Plaintiff/Counterclaim
Defendant Nippon Shinyaku Co., Ltd. and
Counterclaim Defendant NS Pharma, Inc.*

amanda.williamson@morganlewis.com
christopher.betti@morganlewis.com
krista.venegas@morganlewis.com
shon.lo@morganlewis.com
maria.doukas@morganlewis.com
zachary.miller@morganlewis.com
guyaine.hache@morganlewis.com
michael.sikora@morganlewis.com

Eric Kraeutler (admitted *pro hac vice*)
1701 Market Street
Philadelphia, PA 19103
Telephone: 215.693.5000
Fax: 215.963.5001
eric.kraeutler@morganlewis.com

CERTIFICATE OF SERVICE

I certify that on June 5, 2023, I caused a true and correct copy of the foregoing document to be served on the counsel of record listed below via e-mail:

Jack B. Blumenfeld
Megan E. Dellinger
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
mdellinger@morrisnichols.com

/s/ Amy M. Dudash
Amy M. Dudash